II. Remarks

A. Status of the claims

Claims 1, 2, 17 and 18 were amended without prejudice or admission. It is respectfully submitted that support for the amendments can be found, e.g., on page 3, first paragraph, of the specification as filed and in the original claims, and that no new matter was added by virtue of present amendments.

Claims 1, 2 and 5-23 are pending.

B. Rejection under 35 U.S.C. § 102

Claims 1, 2, 5-13, 16, 18 and 20, 21 and 23 were rejected under 35 U.S.C. § 102(b) over WO 90/04965 to Lee ("the Lee patent"). The Examiner stated on page 6 of the Office Action that "[n]altrexone ... is not excluded" by the amendments made in the response filed on August 19, 2009 (i.e., that the "composition is free of a non-permeant opioid antagonist"), and that "the Lee patent continues to teach a transdermal device comprising an opioid analgesic and an opioid antagonist that causes distress to the user when delivered."

The rejection is respectfully traversed.

In an effort to advance prosecution of the present application, independent claims 1, 2 and 18 were amended to recite that the claimed compositions are "free of an opioid antagonist." Applicants respectfully submit that the amendment makes it clear that opioid antagonists (i.e., naltrexone) are excluded from the claimed compositions.

Applicants therefore submit that the disclosure of naltrexone in the Lee patent does not read on the "distressing substance" recited in claims 1, 2 and 18, and that the Lee patent does not teach a composition for the percutaneous administration comprising "a distressing substance" as recited in independent claims 1, 2 and 18.

Accordingly, Applicants submit that the Lee patent cannot anticipate claims 1, 2 and 18, and their dependent claims 5-13, 16, 20, 21 and 23, as it does not teach each and every element of these claims.

Withdrawal of the rejection is respectfully requested.

C. Rejections under 35 U.S.C. § 103

1. The Lee patent in view of U.S. Patent No. 5,891,919 to Blum et al. and U.S. Patent No. 4,175,119 to Porter

Claims 1, 2, 5-13 and 15-23 were rejected under 35 U.S.C. §103(a) over the Lee patent in view of U.S. Patent No. 5,891,919 to Blum et al. ("the Blum patent") and U.S. Patent No. 4,175,119 to Porter ("the Porter patent"). The Examiner stated on page 7 of the Office Action that "the Lee patent discloses the use of naltrexone, an opioid antagonist that despite the amendment continues to be useable in the instant claims."

The rejection is respectfully traversed.

In an effort to advance prosecution, independent claims 1, 2, 17 and 18 were amended to recite that the claimed compositions are "free from an opioid antagonist." Applicants submit that the amendment makes it clear that opioid antagonists (i.e., naltrexone) are excluded from the claimed compositions.

The Lee patent describes a dosage form for the administration of an abusable substance by a transdermal route, the dosage form comprising abusable substance and at least one antagonist for the abusable substance. See, e.g., claim 1. The Lee patent states at page 2, lines 32-33, that the antagonist is to "sufficiently negate the pharmacological effect of the abusable substance." The Lee patent again reiterates on page 4, lines 21-24, that "the antagonist for an abusable substance is a compound or composition which acts on the recipient to prevent or substantially diminish the pharmacological effects of the abusable substance or to substantially delay their manifestation."

Applicants respectfully submit that any composition suggested by the combination of the cited references will necessarily include an abuse negating amount of at least one antagonist for the abusable substance. See, e.g., Lee, page 2, lines 26-35; page 4, lines 21-27; page 6, lines 1-5.

As stated above, opioid antagonists are excluded from compositions of independent claims 1, 2, 17 and 18 of the present application.

Applicants further submit that the skilled person starting with the Lee patent will not arrive at the compositions of claims 1, 2, 17 and 18, e.g., because it will be necessary to replace the antagonist of Lee with a distressing substance which does not act as an antagonist, not just add further distressing substances to the compositions of the Lee patent as asserted by the Examiner, to arrive at the presently claimed compositions. Applicants respectfully submit that the combination of the cited references does not provide a reason for such a replacement.

As stated above, the Lee patent requires antagonists in its compositions, and the opioid antagonists are not part of the presently claimed compositions.

Applicants therefore submit that the skilled person would not have modified the compositions of the Lee patent, by replacing the antagonist with a distressing substance which does not act as an antagonist.

Furthermore, Applicants submit that the cited references do not teach or suggest substituting antagonists of the Lee patent with the compounds described in the Blum patent and the Porter patent, e.g., because compounds described in the Blum patent and the Porter patent are not functionally equivalent to the antagonists of the Lee patent. Applicants submit that the primary mechanism of action of opioid antagonist described in the Lee patent (naloxone and naltrexone) is believed to be a prevention of binding of the opioid agonist to its receptor. Applicants submit that there is nothing in the Lee patent to suggest that a composition having a reduced potential for abuse might be provided by

including a compound which is not an antagonist. Rather the mechanism described in Lee for reducing potential for abuse purportedly depends on the "distressing" compound being an antagonist of an abusable substance. Because the compounds of the Blum patent and the Porter patent are not antagonists of abusable substances, Applicants submit that the compounds of these patents and the Lee patent are functionally different, and that the skilled person would not have a reason to substitute the antagonists of the Lee patent with the compounds of the Blum patent and the Porter patents.

In response to the Examiner's statement on page 7 of the Office Action, that the skilled man would substitute the antagonist of Lee with the distressing compounds described in the Blum patent and the Porter patent, Applicants respectfully reiterate that the mechanism and idea underlying the Lee patent is different from that described in the Blum patent and the Porter patent. The Lee patent purports that it prevents abuse by incorporating a negating amount of an antagonist of an abusable substance into its formulations. The Lee patent emphasises throughout its disclosure that the key property of its abuse deterring compound is that it is an antagonist of an abusable substance, so that the abuse compound can prevent the euphorogenic effects of the abusable substance (e.g., opioid). Applicants respectfully note that the Lee patent does not even mention the fact that nausea, vomiting and headache may be a side effect of an opioid antagonist. Applicants therefore submit that, according to the Lee patent, it is purportedly critical for its abuse deterring compound to be an antagonist, rather than a compound which does not block or prevent euphorigenic effects of abusable substances.

As stated above, the compounds described in the Blum patent and the Porter patent are not antagonists of abusable substances and will not block euphorigenic effects of the opioids.

Accordingly, Applicants submit that the combination of the Lee patent with the Blum patent and the Porter patent does not provide a reason for the skilled man reading the Lee patent to replace its opioid antagonist with a non-antagonist distressing compounds recited in the Blum patent and the Porter patent. Applicants submit that to do

so is to completely go against the overall teaching of the Lee patent which is that the antagonist is purportedly essential. Therefore, Applicants submit that the skilled person will not have substituted the antagonists of Lee with the substances described in the Blum patent and the Porter patent.

Applicants respectfully reiterate that compositions of present claims 1, 2, 17 and 18 are free from opioid antagonists, and that the distressing substances recited in the present claims do not prevent the euphorigenic effects and do not act as opioid antagonists. Applicants respectfully note that if the composition of present claims 1, 2, 17 or 18 is mis-used the abuser suffers a distressing effect in conjunction with the euphorigenic effect that results from the opioid analgesic. The concomitant occurrence of the distressing effect is intended to discourage, or act as a deterrent against the abuser mis-using the composition again. Applicants submit that the cited references alone or in combination do not teach or suggest a dosage form providing a distressing effect in conjunction with the euphorigenic effect as recited in claims 1, 2, 17, and 18.

For the foregoing reasons, withdrawal of the obviousness rejection is respectfully requested.

2. The Lee patent in view of U.S. Patent No. 6,001,390 and Drugs: Facts and Comparisons, entry for Pergolide Mesylate, pages 1621-1624

Claims 1, 2, 5-16, 18 and 20-23 were rejected under 35 U.S.C. § 103(a) over the Lee patent in view of U.S. Patent No. 6,001,390 to Yum et al. ("the Yum patent") and Drugs:Facts and Comparison, entry for Pergolide Mesylate, pages 1621-1624 ("Drug Facts and Comparisons"). The Examiner stated on page 7 of the Office Action that "the Lee patent ... continues to disclose the use of a different and distinct opioid antagonist naltrexone that is not foreclosed or excluded by the instant claims."

Independent claims 1, 2 and 18 were amended to recite that the claimed compositions are "free from an opioid antagonist." Applicants submit that the

amendment makes it clear that opioid antagonists (i.e., naltrexone) are excluded from the claimed compositions.

Applicants submit that the combination of the cited references does not teach or suggest to substitute the antagonist of the Lee patent with a functionally different compounds of the Yum patent and Drug Facts and Comparisons for the reasons given above and presented in the response filed on August 19, 2009, hereby incorporated by reference.

Withdrawal of the rejection is respectfully requested.

III. CONCLUSION

An early and favorable action is earnestly solicited. In view of currently recommended Patent Office policy, the Examiner is invited to contact the undersigned in the event that a telephonic interview would advance the prosecution of this application.

Respectfully submitted,
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